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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,064	04/27/2000	Ruth Elinor Bauhahn	11738.86893	2481

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EXAMINER	
YU, JEANNE C	
ART UNIT	**PAPER NUMBER**
3762	14

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,064	BAUHAHN ET AL.	
	Examiner	Art Unit	
	Jeanne C. Yu	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's amendments filed February 20, 2003 is acknowledged. The claims of record were successfully amended to overcome the art of record, hence a new grounds of rejection is established for the pending claims.

The indicated allowability of claims 9, 19 and 29 is withdrawn in view of a newly discovered reference to Boveja USPN 6,269,270. Rejections based on the newly cited reference follow.

Response to Arguments

2. Applicant's arguments filed February 20, 2003 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8,10-18, 20-28 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann USPN 6,052,624 in view of Boveja USPN 6, 269, 270 B1.

Re claim 1, Mann discloses a method comprised of accessing at least one preset clinician therapy program, or basic operating program (column 8, line 67), stored in the medical device 20 (column 9, line 1). The change of parameters in the basic operating system is read as creating a personalized therapy program from the preset clinician program, or basic operating program

(column 9, lines 2-6). The method further comprises storing the personalized therapy program in the memory 67 of the medical device 20 and executing at least one personalized therapy program (column 9, line 19-23), wherein the personalized therapy program is the modified basic operating program.

Re claims 2 and 3, Mann discloses the method wherein the personalized therapy program comprises at least one personalized therapy setting, or stimulation parameter, wherein the personalized therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 19).

Re claims 4 and 5, Mann discloses the method wherein the programmer 10 executes directional responsive rules in the software and/or electronics (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 6, Mann discloses the method wherein the medical device 20 and the patient programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claim 7 and 8, Mann discloses the method wherein the medical device is an implantable or external neurostimulator (column 4, lines 62-67). A medical device 20 having electrodes 24 (Fig 4) to stimulate the senses is read as a neurostimulator.

Re claim 10, Mann discloses a system comprising a medical device 20 comprising a telemetry block, or receiving coil 62 (Fig 2) and memory 67 (Fig 2) with at least one preset

clinician therapy program, or basic operating program (column 8, line 67); and a patient programmer 10 (Fig 2) comprising a telemetry block, or transmission coil 28 (Fig 2). The programmer 10 is read as being able to allow the creation of at least one personal therapy program, wherein the creation of a therapy program lies in the steps of defining a group of electrodes with the directional control device 12 and characterizing the stimulation pulses for the group of electrodes with the display screen 16 or keyboard 14 (column 9, lines 36-65). The programmer 10 is read as being able to allow storage of at least one personal therapy program in the memory 67 (Fig 2) of the medical device by transmitting the data commands through coils 28 and 62. The programmer 10 is also being read as able to allow execution of at least one personalized therapy program in the medical device 20 by transmitting the electrode group data and characterization data to the medical device 20 where the medical device 20 acts on the received electrode group data to provide the programmed stimulation currents to the group of electrodes (column 10, lines 9-16).

Re claims 11 and 12, Mann discloses the system wherein the personalized therapy program comprises at least one personalized therapy setting, wherein the personalized therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 54).

Re claims 13 and 14, Mann discloses the system wherein the programmer 10 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software and/or electronics (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode

configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 15, Mann discloses the system wherein the patient uses a graphical display screen 16 (Fig 1A, column 10, lines 23-25) and input medium, or joystick 12 (Fig 4, column 11, line 32), to create and store the personalized therapy programs (column 11, lines 6-48). Mann shows the clinician or patient maneuvering the joystick 12 (column 12, lines 46-47) such that the resulting selected electrodes can be visualized on display 32, or display screen 16 (Fig 4).

Re claim 16, Mann discloses the system wherein the medical device 20 and the programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claims 17 and 18, Mann discloses the system wherein the medical device 20 is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 20, Mann discloses a programmer 10 comprising an input medium 12 (Fig 1A) and a telemetry block 28 (Fig 3). The stimulator processor circuit 52 (Fig 2) is read as a controller able to create at least one personalized therapy program from the electrode group data and characterization data, received from the directional control device 12 and/or display screen 16 (column 9, lines 38-64), processing the data so that appropriate commands may be sent to the medical device 20 (column 9, line 67 and column 10, lines 1-2), and storing at least one personalized therapy program in the memory 67 (Fig 2) of the medical device 20 (column 9, lines 2-6).

Re claims 21 and 22, Mann discloses the programmer 10 wherein the personalized therapy program comprises at least one personalized therapy setting, wherein the personalized

therapy setting comprises of at least one of an amplitude, a rate, a pulse width, a pulse frequency, electrode polarities or directional sequence (column 9, line 54).

Re claims 23 and 24, Mann discloses the programmer 10 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software, or computer instructions (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm.

Re claim 25, Mann discloses the programmer 10 wherein the patient uses a graphical display screen 16 (Fig 1A) and input medium, or joystick 12 (Fig 1A), to create and store the personalized therapy programs (column 11, lines 6-48). Mann shows the clinician or patient maneuvering the joystick 12 (column 12, lines 46-47) such that the resulting selected electrodes can be visualized on display 32, or display screen 16 (Fig 4).

Re claim 26, Mann discloses the programmer wherein the medical device 20 and the patient programmer 10 communicate via telemetry (column 8, lines 29-32) between transmission coil 28 and receiving coil 62.

Re claims 27 and 28, Mann discloses the programmer wherein the medical device is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 30, Mann discloses a patient programmer 10 comprising an input medium 12 (Fig 1A). As described on page 11, line 11, a means for creating a personalized therapy program may be the controller 55. The stimulator processor circuit 52 is read as having the same

functional capabilities as the controller 55 because Mann discloses the processor circuit 52 capable of creating a personal therapy program from the electrode group data and characterization data, received from the directional control device 12 and/or display screen 16 (column 9, lines 38-64), processing the data so that appropriate commands may be sent to the medical device 20 (column 9, line 67 and column 10, lines 1-2), and storing at least one personalized therapy program in the memory 67 (Fig 2) of the medical device 20 (column 9, lines 2-6). As described on page 11, lines 12, a communication means, connected to the means for creating, for storing and executing (i.e. the processor 52) at least one personalized therapy program in a medical device is the telemetry block 65. The transmission coil 28 is read as having the same functional capabilities as the telemetry block 65 because Mann discloses the medical device 20, or receiving coil 62, receiving transmitted data from the programmer 10, or transmission coil 29 (column 8, lines 30-32).

Re claim 31, Mann discloses a programmer 10 comprising an input medium, which may be a display screen 16, directional control device 12, keyboard 14, and/or other I/O devices such as 35, 37, 39 (Fig 4) (column 9, lines 40, 60, 64), for receiving a plurality of personalized therapy settings from a patient (column 12, lines 46-47). Electrode group data (column 9, line 67) and characterization data (column 9, line 58) are read as personal therapy settings, wherein each personalized therapy setting provides settings for a plurality of parameters of a therapy program, or basic operating program (column 8, line 67), selected from the group consisting of an amplitude, a pulse rate, a pulse width, a pulse frequency (column 9, lines 19, 54-55), an electrode polarity and a directional sequence (column 12, lines 51-65). The transmission coil 28 (Fig 2) is read as a telemetry block. The stimulator processor 52 is read as a controller able to create a

personalized therapy program for each personalized therapy setting, by processing the characterization and electrode group data received from the patient (column 9, lines 66-67 and column 10, lines 1-2), and cause the personalized therapy programs to be stored in the memory 67 of the medical device 20 (column 9, lines 2-6) via the telemetry block 28 (column 10, lines 9-13), wherein the medical device 20 then acts on the data received by providing the programmed stimulation currents to the group of electrodes selected by the patient through the directional device 12 (column 10, lines 13-16). The operator, or patient, making adjustments in the pulse width, pulse amplitude, and pulse repetition rate (column 14, lines 45-47) is read as the patient subsequently instructing the medical device 20 via the patient programmer 10 to provide therapy to the patient in accordance with one of the personalized therapy programs, i.e. after the electrode group has been maneuvered to the desired area using the joystick 12.

Re claims 32 and 33, Mann discloses the programmer 10 wherein the controller 52 executes directional responsive rules, or a personalized therapy algorithm and timing algorithm, in the software (column 5, lines 31-33). These directional responsive rules, or selection software algorithms (column 12, lines 41-42), are read as both a personalized therapy algorithm and timing algorithm because it allows the patient to automatically adjust the electrode configuration (column 5, lines 33-37), wherein the automatic adjustment would require a timing algorithm and is in itself a personalized therapy algorithm. Mann clearly discloses the controller 52 processing, or executing, characterization and electrode group data (column 9, lines 66-67) defined from the selection software algorithms (column 12, lines 40-41) so that the appropriate commands may be sent to the medical device 20 (column 10, lines 1-2).

Re claim 34, Mann discloses the programmer wherein the input medium 16 is a graphical screen interface, or touch-sensitive screen (column 9, lines 60-63 and column 11, line 34-37), to create the personalized therapy program.

Re claims 35 and 36, Mann discloses the programmer wherein the telemetry block 28 is capable of communicating a medical device 20 (column 10, lines 8-13), wherein the medical device 20 is an implantable or external neurostimulator (column 4, lines 62-67).

Re claim 37, Mann discloses stimulation parameters, or the personalized therapy program, based on user activity, or patient's activity (column 2, lines 13-14). Although Mann does not specifically mention this factor in the preferred embodiment, a reference is not limited to its preferred embodiment, but must be evaluated for all of its teachings, including teachings of non-preferred embodiments. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

Mann does not disclose expressly accessing more than one preset clinician therapy program. Boveja teaches that is it known to access more than one predetermined program on a medical device or external stimulator 42 (Fig 1A) (column 11, lines 7-13). Mann and Boveja are analogous art because they are from the same field of endeavor, i.e. controlling implantable stimulators. At the time of the invention, it would have been obvious to modify the programming system of Mann with the pre-packaged programs of Boveja. The motivation for doing so would have been to provide predetermined levels of therapy aggressiveness with personalized parameter settings for a patient (Mann, column 11, lines 56-61).

3. Claims 9, 19 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann USPN 6,052,624 in view of Boveja USPN 6, 269, 270 B1 as applied to the rejected claims above, and further in view of Barreras, Sr. et al. USPN 5,941,906.

As discussed in section 2 of this action, Mann in view of Boveja discloses the claimed invention except for the medical device being selected from a group consisting of a pacemaker, a defibrillator, a cochlear implant, an implantable diagnostic device and an implantable pump. Barreras teaches that it is known that an implantable tissue stimulator may be a pacemaker or defibrillator (column 1, lines 21-29). Mann and Barreras are analogous art because they are from the same field of endeavor, i.e. implantable tissue stimulators. At the time of the invention, it would have been obvious to modify the tissue stimulator of Mann with a pacemaker as taught by Barreras. The motivation for doing so would have been to restore a sick human heart to a normal rhythm (Barreras, column 1, lines 24-25).

4. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann USPN 6,052,624 in view of Boveja USPN 6, 269, 270 B1 as applied to the rejected claims above, and further in view of Wernicke et al. (USPN 5,231,988).

As discussed in section 2 of this action, Mann in view of Boveja discloses the claimed invention except for a personalized therapy program based on time of day or associated with a particular time of day. Wernicke et al. discloses a therapy program to activate a neurostimulator based on a particular time of day, i.e. after meal periods (column 4, lines 38-43). Mann and Wernicke et al. are analogous art because they are from the same field of endeavor, i.e. programming stimulation parameters of a medical device. At the time of the invention, it would .have been obvious to a person of ordinary skill in the art to combine the therapy program of Mann with the therapy program based on time of day or associated with a time of day of Wernicke et al. The motivation for doing so would have been to secrete insulin in a diabetic

patient after an increase in glucose level due to food consumption (Wernicke et al. column 8, lines 4-23).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeanne C. Yu whose telephone number is 703-305-7569. The examiner can normally be reached on Monday-Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JCY
April 19, 2003

ANGELA D. SYKES
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